PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Annaliesa S. Anderson, *et al.*		
Serial No.:	10/564,458	Case No.: 21569YP	Art Unit: 1645
Filed:	January 12, 2006		Examiner: Devi, Sarvamangala
For:	POLYPEPTIDES FOR INDUCING A PROTECTIVE IMMUNE RESPONSE AGAINST STAPHYLOCOCCUS AUREUS		

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

PETITION TO WITHDRAW FINALITY OF OFFICE ACTION MAILED NOVEMBER 24, 2009

Sir:

Pursuant to 37 C.F.R. § 1.181, Applicants request the finality of the office action mailed November 24, 2009 be withdrawn as premature. The November 24, 2009 office action for the first time in the prosecution of the present application included a written description rejection. The rejection was directed to claim descriptions provided in claims pending before the first office action. The written description rejection was not necessitated by claim amendment or the submission of an Informational Disclosure Statement.

No fees are believed due in connections with this petition. If any fees are required, Applicants request and authorize that the appropriate fees be taken from Merck Deposit Account No. 13-2755.

Statement of Facts

A summary of the prosecution starting with a response to the July 18, 2008 restriction requirement is as follows:

1. A response to a restriction requirement was mailed August 18, 2008. All of the claims under examination depended directly, or indirectly, from a claim that included reference to

comprising an amino acid sequence with at least a 90% sequence identity to SEQ ID NO: 1. Several of the dependent claims included additional descriptions with respect to possible differences from SEQ ID NO: 1 by indicating, for example, at least 94% sequence identity; or up to 5, up to 10, or up to 25 amino acid alterations from SEQ ID NO: 1.

2. Examples of claims in the August 18, 2008 providing sequence identity language or possible numbers of alterations are claims 1, 2, and 33-35:

> Claim 1 (original): A polypeptide immunogen comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1, wherein said polypeptide provides protective immunity against *S. aureus* and wherein if one or more additional polypeptide regions are present said additional regions do not provide a carboxyl terminus containing amino acids 609-645 of SEQ ID NO: 2.

(Response filed August 18, 2008 at page 2.)

> Claim 2 (original): The polypeptide of claim 1, wherein said polypeptide consists of an amino acid sequence at least 90% identical to SEQ ID NO: 3 or a fragment thereof comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1.

(Response filed August 18, 2008 at page 2.)

> Claim 33 (New): The polypeptide immunogen of claim 3, wherein said polypeptide is SEQ ID NO: 1 or differs from SEQ ID NO: 1 by up to 25 amino acid alterations.

(Response filed August 18, 2008 at page 4.)

> Claim 34 (New): The polypeptide immunogen of claim 33, wherein said polypeptide is SEQ ID NO: 1 or differs from SEQ ID NO: 1 by up to 10 amino acid alterations.

(Response filed August 18, 2008 at page 5.)

> Claim 35 (New): The polypeptide immunogen of claim 34, wherein said polypeptide is SEQ ID NO: 1 or differs from SEQ ID NO: 1 by up to 5 amino acid alterations.

(Response filed August 18, 2008 at page 5.)

3. A non-final office action was mailed December 15, 2008. The December 15, 2008 office action did not provide any written description rejections.

4. Applicants discussed the present application with the Examiner in an interview on February 24, 2009.

5. Applicants filed a response to the December 15, 2008 office action on March 13, 2009. The March 13, 2009 response amended claims 1, 3-8, and 33-46; canceled claims 2, 10,

17, 18, 20, 21, 24, 25, 27, and 29; added new claims 47-54; amended the specification; and provided a replacement for Figure 1A.

6. The March 13, 2009 response included amending claim 1 to reference "purified", and incorporating the description previously provided in claim 2 along with a clarification to the claim 2 language. Claim 1 was amended as follows:

> Claim 1 (currently amended): A purified polypeptide immunogen consisting of either (a) ~~comprising~~ an amino acid sequence at least 90% identical to SEQ ID NO: 3, or (b) a fragment of said amino acid sequence at least 90% identical to SEQ ID NO: 3, where said fragment comprises an amino acid sequence at least 90% identical to SEQ ID NO: 1;~~,~~ wherein said polypeptide immunogen provides protective immunity against *S. aureus* ~~and wherein if one or more additional polypeptide regions are present said additional regions do not provide a carboxyl terminus containing amino acids 609-645 of SEQ ID NO: 2~~.

(Response filed March 13, 2009 at page 8.)

7. The March 13, 2009 response also included claims with editorial revisions directed to antecedent bases. For example, claims 4 and 33-35, all of which ultimately depended from claim 1, were amended as follows:

> Claim 4 (currently amended): The polypeptide immunogen of claim 3, wherein said polypeptide immunogen consists of an amino acid sequence at least 94% identical to SEQ ID NO: 1, SEQ ID NO: 3 or SEQ ID NO: 42.

(Response filed March 13, 2009 at page 8.)

> Claim 33 (currently amended): The polypeptide immunogen of claim 3, wherein said polypeptide immunogen is SEQ ID NO: 1 or differs from SEQ ID NO: 1 by up to 25 amino acid alterations.

(Response filed March 13, 2009 at page 9.)

> Claim 34 (currently amended): The polypeptide immunogen of claim 33, wherein said polypeptide immunogen is SEQ ID NO: 1 or differs from SEQ ID NO: 1 by up to 10 amino acid alterations.

(Response filed March 13, 2009 at page 9.)

> Claim 35 (currently amended): The polypeptide immunogen of claim 34, wherein said polypeptide immunogen is SEQ ID NO: 1 or differs from SEQ ID NO: 1 by up to 5 amino acid alterations.

(Response filed March 13, 2009 at page 9.)

8. The Patent Office mailed a Notice of Non-Compliance on July 7, 2009, indicating the response filed March 13, 2009 was non-responsive. The examiner indicated it was not clear in the amendment to claim 1 whether a deletion or addition of a comma was intended, and that an annotated drawing showing changes, for the drawing being corrected, was required.

9. The March 13, 2009 amendment to claim 1 clearly intended to delete the comma in question and there was no prior requirement to present an annotated drawings showing corrections. Claim 1 presented prior to the amendment contained the comma in question, clearly evidencing that an addition was not intended in the March 13, 2009 amendment. (See claim 1 in the Response filed August 18, 2008 at page 2.) Additionally, in the amendment, a semicolon preceding the comma was added by an underline, and a line is clearly presented above the comma. (See claim 1 in the Response filed March 13, 2009 at page 8.)

10. On July 13, 2009, Applicants responded to the Notice of Non-Compliance within the one-month period set for a response. The July 13, 2009 amendment provided double brackets around the comma and an annotated figure showing the corrections.

11. The Patent Office mailed a final rejection on November 24, 2009. The final rejection for the first time in the prosecution of the present application, provided a written description rejection.

12. The language upon which the November 24, 2009 written description rejection was based, was present in the claims prior to the non-final rejection of December 15, 2008. (See for example, paragraphs numbers 1, 6 and 7 *supra.*)

Summary

The November 24, 2009 office action was improperly made final. The November 24, 2009 office action for the first time in the prosecution of the present application provided a written description rejection. The percent identity and number of possible alterations language, upon which the written description rejection was based, was present in claims pending prior to the December 15, 2008 non-final office action. The amendments provided in the response to December 15, 2008 did not necessitate the written description rejection.

Respectfully submitted,

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